DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

June 18, 2003

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Nadine M. Donahue,
CEO and President
Bioscan, Inc.
45 Dusty Trail Drive
Placitas, New Mexico 87043

Ref. #: DEN-03-18

Dear Ms. Donahue:

We are writing to you because of the regulatory problems involving the BioFind III (or Biofind), BioPack II (or BioPack), Light Patch, Spinal Pad, and Knee Saver products, which are manufactured or distributed by your firm. These products are medical devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). Your firm fails to comply with applicable premarket notification requirements and the agency's Quality System/Good Manufacturing Practice Regulation.

A. Violation of premarket notification requirements

Information on your firm's website at http://www.bioscanlight.com indicates violation of premarket notification requirements. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. However, your firm has not submitted a premarket notification (510(k)) submission and obtained marketing clearance before it began marketing the Knee Saver by offering it for sale on your website. In addition, your firm may be marketing a new product called the Podiatric LED Device: Neuropathy Boot. This product appears on your firm's website. We have not received a premarket notification submission for this product and we request that you provide information on the marketing status of this device. We also urge you to review all of the products that your firm distributes to assure that required premarket clearances have been obtained.

Also, our records show that, while your firm submitted premarket notification (510(k)) submissions for the BioFind III (or Biofind), BioPack II (or BioPack), Light Patch, and Spinal Pad devices, you are marketing these devices for many new indications for use for which you have not obtained marketing clearance. Examples of these new indications for use, taken from your firm's website, through which customers can buy the products, include the following: treatment of corneal ulcers, stimulates the release of adenosine triphosphate (ATP), increases RNA and DNA synthesis, increases phagocytosis, and stimulates acetylcholine release. These are major changes or modifications in the intended use of these devices and require new premarket notification submissions (21 CFR 807.81(a)(3)(ii)).

In general, your BioPack II (or BioPack), Light Patch, and Spinal Pad devices containing infrared diodes were cleared as infrared lamps that provide topical heating in a therapeutic range, not for photonic or light therapy; and the visible red diodes that do not provide topical heating were not to be discussed in your device labeling, etc. Specifically, the only indications for use that these devices were cleared for are: Use whenever hot applications are desirable for personal comfort and whenever recommended by a licensed medical professional, providing temporary relief of minor aches and pains in muscles and joints, aiding in relaxation of muscles, helping to provide for a temporary improved range and freedom of motion due to muscle relaxation and temporary minor pain relief, and providing a temporary increase in local blood circulation.

With respect to the BioFind III (or Biofind) device, the only cleared indication for use is for galvanic skin measurement for biofeedback information. Also, your firm was informed by FDA during the 510(k) review process in 2001 that scanning the whole body and not just two points in the body is a new intended use for which the predicate device was not cleared, and your firm subsequently agreed to delete references to the scanning as well as to limit other specified claims.

The kind of information your firm needs to submit in order to obtain premarket clearance for the Knee Saver and for the new intended uses for your other products is described on the agency's Internet website at http://www.fda.gov/cdrh/devadvice/3122.html. Please be advised that your Premarket Notification submissions should include valid scientific data to support any claims outside of the above listed cleared claims/indications for infrared lamp devices and for the BioFind III. The FDA will evaluate this information and decide whether your products may be legally marketed.

Your promotion and introduction into interstate commerce of the BioFind III (or Biofind), BioPack II (or BioPack), Light Patch, Spinal Pad, and the Knee Saver for these uncleared indications render them adulterated under section 501(f)(1)(B) of the Act, for failure to obtain FDA premarket approval, and misbranded under section 502(o) of the Act, for failure to notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the act is

deemed to be satisfied when a premarket approval application (PMA) is pending before the agency (21 CFR 807.81(b)).

You should know that these serious violations of the law may result in the FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. In addition, United States federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected. It is necessary for you to take action on this matter now.

B. Violation of quality system regulation requirements

Additionally, for your information, on September 17, 25, and 26, 2002, an investigator from the FDA Albuquerque, New Mexico office conducted an inspection of your establishment located at 45 Dusty Trail Drive, Placitas, New Mexico 87043. The inspection revealed that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of these devices are not in conformance with the Quality System (QS) Regulation, as specified in 21 CFR, Part 820. These deviations from the QS Regulation cause your products to be adulterated within the meaning of section 501(h) of the Act. Significant deviations include, but are not limited to, the following:

1. Failure to establish and maintain device master records (DMR) for the BioFind, BioPack, Light Patch, Spinal Pad, and Knee Saver devices, which include:
   a. device specifications;
   b. production process specifications;
   c. quality assurance procedures and specifications;
   d. packaging and labeling specifications and;
   e. installation, maintenance and servicing procedures and methods;

   as required by 21 CFR 820.181.

2. Failure to establish and maintain device history records (DHR), for each batch, lot, or unit, to demonstrate that the device is manufactured in accordance with the DMR and the requirements of 21 CFR Part 820, as required by 21 CFR 820.184.

3. Failure to establish and maintain a quality system that is appropriate for the specific medical devices designed and manufactured by your firm, which includes:
   a. quality policy;
   b. organizational structure;
   c. management review of the quality system;
   d. a quality plan which defines the quality practices, resources and activities;

e. a quality system procedure;
as required by 21 CFR 820.5 and 820.20.

4. Failure to establish procedures for quality audits, and to conduct audits to determine the effectiveness of the quality system and assure that it meets established requirements, as required by 21 CFR 820.22.

5. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, and for ensuring that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR 803, Medical Device Reporting (MDR), as required by 21 CFR 820.198.

6. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100.

7. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30.

8. Failure to establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed, as required by 21 CFR 820.160.

9. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90.

10. Failure to establish and maintain procedures for identifying product during all stages of receipt, production, distribution and installation to prevent mix-ups, as required by 21 CFR 820.60.

11. Failure to establish and maintain procedures to control all documents specified by the Quality System regulation, as required by 21 CFR 820.40.

12. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.

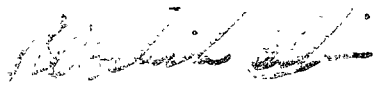
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 provided to your firm at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. We have received a letter from you dated October 1, 2002, and a

letter from Mr. Peter J. Chase, dated March 3, 2003. The responses in these two letters are not adequate; they did not fully address or describe how you have corrected or will correct the noncompliances noted above.

Please let this office know in writing within 15 working days from the date you receive this letter, the steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these deficiencies from occurring again. If you need more time, let us know why and when you expect to complete your corrections.

Please address your response and any questions you may have regarding this letter to William H. Sherer, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087, (303) 236-3051.

Sincerely,



B. Belinda Collins
District Director